



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,240	02/17/2004	Malcolm I. Falconer	C-314 DIV	9660
26079	7590	06/24/2005	EXAMINER	
BRISTOL-MYERS SQUIBB COMPANY 100 HEADQUARTERS PARK DRIVE SKILLMAN, NJ 08558			BOGART, MICHAEL G	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

28

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/780,240	FALCONER, MALCOLM I.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael G. Bogart	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 24, 25, 28-30 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 24, 25, 28, 30 and 33 is/are rejected.
- 7) ☒ Claim(s) 29 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/370,305.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Drawings***

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

It is noted that in the Petition Decision dated 13 September 2004 that applicants were precluded from being having the figures considered as part of the original application *as filed*. However, because the figures were included in parent application 09/370,305, they may be resubmitted as an amendment without violating the prohibition against new matter.

### ***Claim Objections***

Claim 7 is objected to because of the following informalities: In line 2, "aperture" should be pluralized. Appropriate correction is required.

In the preliminary amendment dated 17 February 2004, applicants indicate that claims 1-12, 24-25, 28-30 and 33-34 are presently pending. However, claims 35-37 of parent application 09/370,305 have not been addressed. In that parent application, claims 35-37 were subject to a restriction from 1-12, 24-25, 28-30 and 33-34. Applicants should clarify the status of these claims as pending, withdrawn or canceled. For the purposes of this action, they are not addressed on the merits.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 rejected under 35 U.S.C. § 102(b) as being anticipated by Leise, Jr. (US 4,938,750).

Regarding claim 1, Leise, Jr. teaches an apparatus comprising a controllable flow rate, filtered vent (20) for an ostomy pouch (10), the vent (20) having a plurality of outlets (30) and a device (24, 30) for controlling the rate of flow of gas through the vent (30), the device (24, 30) comprising adhesive sticker means (32) which can be positioned and, re-positioned (32) to selectively expose or cover one or more of the plurality of outlets (30), and thereby regulate variably the rate of flow of gas according to the outlets (30) exposed (figure 1).

Regarding claim 2, Leise, Jr. teaches that the flow rate is controllable according to the number of outlets (30) exposed.

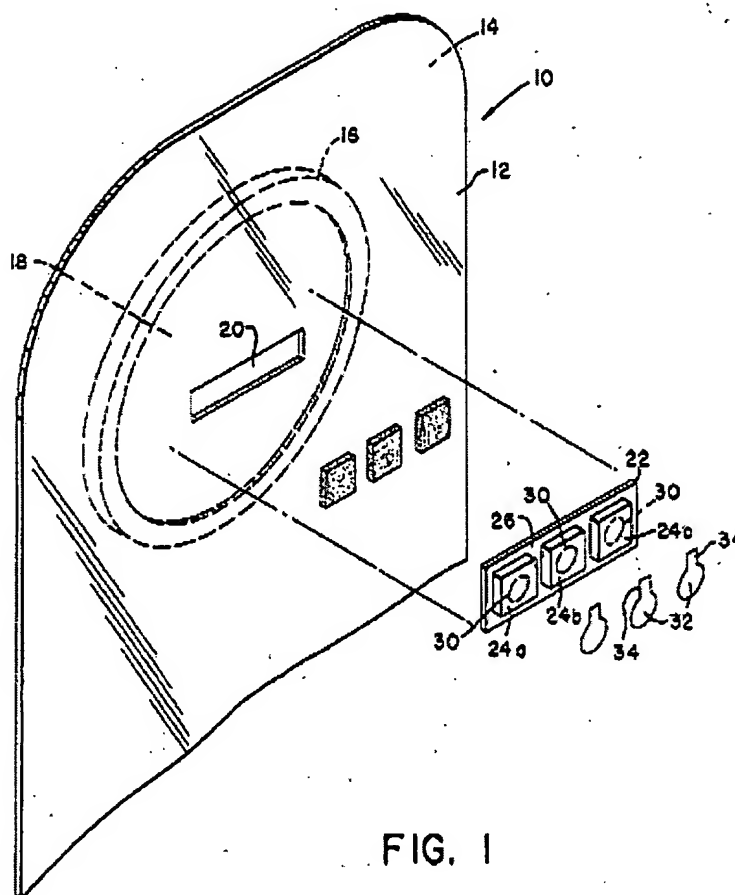
Regarding claim 3, Leise, Jr. teaches a three part sticker means (32) that is of sufficient size to cover all of the outlets (30).

Regarding claim 4, Leise, Jr. teaches that one or more of the outlets (30) comprises a hole (30) in a layer (22, 24) to which the sticker means is adherable.

Regarding claim 5, Leise, Jr. teaches that one or more of the outlets (30) comprises a clearance (26) between one or more outlets (30).

Art Unit: 3761

Regarding claim 6, Leise, Jr. teaches a filter comprising a flow restricting layer (28) provided upstream of the outlets (30).



Regarding claim 7, Leise, Jr. teaches that the vent (20) means having a plurality of apertures (30) for outletting gas through said vent (20), and a flow restricting layer (28) upstream of the aperture means (30).

Regarding claims 8 and 9, Leise, Jr. teaches that the aperture means (30) comprises a plurality of individual apertures (30)(figure 1).

Art Unit: 3761

Regarding claim 10, Leise, Jr. teaches that the sticker means (32) is positioned or positionable to selectively block all of the area of the aperture means (30) by using all three sticker means subcomponents.

Regarding claim 11, Leise, Jr. teaches that the flow restricting layer (28) comprises microporous material.

Regarding claim 12, Leise, Jr. teaches that the pouch (10) comprises a first wall (12) provided with the vent (20) and with a comfort layer (22).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leise, Jr. as applied to claims 1, 2 and 4-12 above, and further in view of Eastman (EP 0 231 508 A2).

Leise, Jr. fails to teach an adhesive skin attachment wafer including a plurality of cutting guidelines.

Eastman teaches an ostomy pouch (10) having an adhesive wafer (22) with a plurality of circular (42) and noncircular (43) cutting guidelines.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the adhesive wafer with cutting line of Eastman to the ostomy device of Leise, Jr. in

Art Unit: 3761

order to provide an adjustable attachment means for attaching the device to wearers of various sizes.

Regarding, claim 33, Eastman teaches a cutting line (43) having a non-circular, non-racetrack shape.

### *Allowable Subject Matter*

Claims 29 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Larry Schwartz may be reached at phone number (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

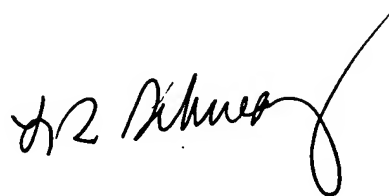
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 3761

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart  
20 June 2005



Larry I. Schwartz  
Supervisory Patent Examiner  
Group 3700